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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,429	01/04/2002	Jeffrey H. Burbank	266/153	7194

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PATENT DEPARTMENT
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EXAMINER

WIGGINS, JOHN DAVID

ART UNIT	PAPER NUMBER
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2856

DATE MAILED: 05/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/037,429

Applicant(s)
Jeffrey H. Burbank

Examiner
David J. Wiggins

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2856



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on January 04, 2002 [Application for US PTO patent received]

2a) ☐ This action is FINAL.

2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-64 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) 17-20 is/are allowed.

6) ☒ Claim(s) 1-4, 6-11, 16, 21-24, 26-37, 43-46, and 48-59 is/are rejected.

7) ☒ Claim(s) 5, 12-15, 25, 38-42, 47, and 60-64 is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on Jan 4, 2002 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

4) ☐ Interview Summary (PTO-413) Paper No(s): _____

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) ☐ Notice of Informal Patent Application (PTO-152)

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s): _____

6) ☐ Other:

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Part III DETAILED ACTION

Examiner's Office Action

Drawings

1. *This application has been filed with formal drawings which have been judged acceptable on their technical merit by the Examiner, while also judged to possess acceptable quality for meeting drawing requirements of any Patent Drawing Review to be done by a US PTO draftsman after the 01/04/2002 filing date.*

Specification

2. The disclosure is objected to because of the following informalities:

On Page 18, line 21 of the specification; after the words "with each", please consider inserting the following term:

--- other --- OR --- component ---

On Page 34, line 07 of the Abstract Sheet; after the words

"preventing leaks", please consider inserting the following

phrase: --- and/or air infiltrations ---

On Page 34, line 13 of the Abstract Sheet; after the word

"loudness", please consider inserting the following phrase:

--- , frequency range ---

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On Page 34, line 14 of the Abstract Sheet; after the words "when a leak", please consider inserting the following phrase:

--- , air bubble or air infiltration ---

On Page 21, claim 1, line 05; after the words "detecting air", please consider inserting the following phrase:

--- or bubbles ---

On Page 21, claim 1, line 03; before the word "fluid", please consider inserting the following phrase:

--- a blood, plasma or liquid ---

On Page 21, claim 2, line 02; before the word "fluid", please consider inserting the following term:

--- liquid ---

On Page 22, claim 5, line 02; after the word "flow", please consider inserting the following term:

--- direction ---

On Page 22, claim 6, line 03; after the words "fluid detector", please consider inserting the following phrase:

--- connected thereto ---

On Page 22, claim 7, line 02; before the word "tubing", please consider inserting the following phrase:

--- a line of ---

On Page 22, claim 9, line 03; after the word "funnel", please consider inserting the following phrase:

--- that leads ---

On Page 23, claim 13, line 01; after the word "device", please consider inserting the following phrase:

--- that is ---

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On Page 23, claim 10, line 09; after the words "to detect",
please consider inserting the following phrase:

--- or bubbles ---

On Page 22, claim 10, line 03; before the word "fluid", please
consider inserting the following phrase:

--- a blood, plasma or liquid ---

On Page 23, claim 10, line 12; before the word "fluid", please
consider inserting the following term:

--- liquid ---

On Page 23, claim 11, line 03; before the words "blood leaking",
please consider inserting the following term:

--- any ---

On Page 23, claim 12, line 02; after the word "flow", please
consider inserting the following term:

--- direction ---

On Page 23, claim 14, line 03; before the words "blood leaking",
please consider inserting the following term:

--- any ---

On Page 24, claim 16, line 02; after the words "presence of air",
please consider inserting the following term:

--- or bubbles ---

On Page 24, claim 17, line 04; before the words "blood outside",
please consider inserting the following phrase:

--- any presence of ---

On Page 25, claim 18, line 02; before the words "fluid sensor",
please consider inserting the following term:

--- liquid ---

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On Page 25, claim 19, line 03; after the words "reverse flow",
please consider inserting the following term: --- direction ---

On Page 25, claim 20, line 04; before the words "leaking fluid",
please consider inserting the following term: --- any ---

On Page 25, claim 21, line 03; before the word "infiltration",
please consider inserting the following term: --- any ---

On Page 25, claim 21, line 05; before the word "leakage", please
consider inserting the following term: --- any ---

On Page 26, claim 23, line 02; before the word "infiltration",
please consider inserting the following term: --- any air ---

On Page 26, claim 23, line 04; before the words "leaking fluid",
please consider inserting the following term: --- any liquid ---

On Page 26, claim 25, line 01; please consider replacing the
incorrect reference to "in claim 25" with the following intended
reference label: --- in claim 24 ---

On Page 26, claim 25, line 02; after the word "flow", please
consider inserting the following term: --- direction ---

On Page 27, claim 32, line 03; before the words "blood outside",
please consider inserting the following term: --- any ---

On Page 27, claim 32, line 02; after the words "infiltration of",
please consider inserting the following clause:

--- any air bubbles or ---

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On Page 28, claim 38, line 04; after the words "presence of",
please consider inserting the following clause:--- any liquid ---

On Page 28, claim 37, line 03; after the words "presence of",
please consider inserting the following clause:--- any liquid ---

On Page 28, claim 39, line 02; after the word "flow", please
consider inserting the following term: --- direction ---

On Page 28, claim 40, line 03; after the word "flow", please
consider inserting the following term: --- direction ---

On Page 28, claim 40, line 02; after the words "infiltration of",
please consider inserting the following clause:

--- any air bubbles or ---

On Page 29, claim 40, line 02; before the words "blood outside",
please consider inserting the following term: --- any ---

On Page 29, claim 41, line 02; before the words "sensor located",
please consider inserting the following clause:

--- blood, plasma or liquid sensitive ---

On Page 29, claim 42, line 03; before the words "fluid sensor",
please consider inserting the following clause:

--- blood, plasma or liquid ---

On Page 29, claim 43, line 02; before the words "fluid
processing", please consider inserting the following clause:

--- blood or liquid ---

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On Page 29, claim 43, line 04; before the word "infiltration",
please consider inserting the following term: --- any ---

On Page 29, claim 43, line 06; before the words "fluid detector",
please consider inserting the following term: --- liquid ---

On Page 29, claim 43, line 07; before the word "fluid", please
consider inserting the following term: --- liquid ---

On Page 29, claim 45, line 02; please consider replacing the word
"infiltration" with the following phrase:

--- any infiltration of air ---

On Page 30, claim 50, line 07; before the words "sensors
configured", please consider inserting the following clause:

--- two or more ---

On Page 31, claim 51, line 03; before the word "signal", please
consider inserting the following term: --- control ---

On Page 31, claim 52, line 04; before the word "signal", please
consider inserting the following term: --- control ---

On Page 31, claim 53, line 02; before the word "signal", please
consider inserting the following term: --- control ---

On Page 31, claim 56, line 04; after the words "thereto and",
please consider inserting the following clause:

--- also including ---

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On Page 31, claim 56, line 03; before the word "signal", please consider inserting the following term: --- control ---

On Page 32, claim 56, line 02; before the word "signal", please consider inserting the following term: --- control ---

On Page 32, claim 58, line 03; please consider replacing the phrase "either of either of" with the following words: --- either of ---

On Page 32, claim 60, line 02; after the words "air sensor", please consider inserting the following phrase: --- or bubble sensor ---

On Page 33, claim 62, line 03; before the words "air into", please consider inserting the following term: --- any ---

Appropriate correction is requested or required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

4. Claims 1-2, 3-4, 6-7, 8-9, 10-11, 16, 21-24, 26-27, 28-37, 43-46, 48-49 and 50-59 are rejected under 35 U.S.C.

§ 103 as being unpatentable over Polaschegg, H-D., in view of O'Keeffe, T.G. et al. and Johnson, D.A. et al. in view of Askwith, H. et al., in view of Saugues, A. et al..

The prior art of Polaschegg teaches an extracorporeal blood treatment machine and dialysis fluid analysis means that uses a blood circuit having a positive pressure portion and negative pressure portion in a blood leakage detecting apparatus that covers most features of the instant invention except for (1) having a gas, bubble or air infiltration sensing means [disposed in some other part of the blood circuit than where the blood leak detector 128 in Figure 1 of Polaschegg is located]; and except for (2) having both a gas/air sensitive means and liquid loss sensitive means mounted on the liquid circuit for monitoring/ distinguishing two different types of leaks while discerning the occurrence of any leak in a liquid circuit flowpath; and except for (3) having a leak occurrence trigger signal and alarm system

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that can warn machine operators and alter control of some system component [pump] in the event of a fluid leakage event [bubble]; and except for (4) having a funnel placed underneath the blood processing machine in order to channel any leaking blood towards the liquid leakage detector. However, the feature of placing a funnel with liquid detector beneath a leaking device is a standard practice that prods the Examiner into considering it Notoriously Old and Well Known to detect fluid by first collecting the fluid and then guiding it in a gravity-driven flow towards the adjacent fluid detector; i.e.- the funnel lips of a rain gauge collector with an electronic water level detector; certainly the use of a catch pan, drain pan or inverted funnel to magnify ~~of~~ the amount of a liquid sample taken before a subsequent detection, chemical analysis, mass weighing or presence/absence decision is common throughout the sampling arts. Also, the prior art of Saugues discloses the concept of providing a trigger signal, an alarm action and a pump stopping response into a air/gas bubble in a flowing fluid line detection system- please see his Columns 1 & 3 for relevant details. It would have been obvious for the skilled medical technology artisan to consider installing an alarm capability into a blood flowline because of the health risks & dangers imposed upon a hospital

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patient due to any air/gas bubbles entrained within the body's bloodflow. Additionally, O'Keeffe et al. reveals the feature of disposing fluid sensors in one part of a liquid fluid flowpath that is separate from another distinct part of the total fluid circulation flowpath; i.e.- a gas concentration sensor or a moisture sensor that provides physical property measurements for the circulating liquid- please see their Figures 1 & 4 along with Columns 1, 3 & 6 for pertinent details; while Johnson et al. teaches the use of an air infiltration/air bubble detector in a blood flowline so as to ensure safe dialysis & blood treatment operations for a hospitalized patient- please see their Columns 1-5 along with Figures 1-2 for relevant details. It would have been obvious to one of ordinary skill in the art to consider placing an air infiltration detector into the prior art system of Polaschegg [that already has a blood leakage detector] and at a different location than the blood leakage detector in the system of Polaschegg since the two leakage modes are different in cause & effect from each other [air fluid goes into the flowline for one leakage finding mode, while liquid fluid goes out from the flowline for the other leakage finding mode- the liquid leakage mode is enhanced at high fluid pressures, while the air leakage mode is enhanced at vacuum states or low pressures]. Note that

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Askwith et al. suggest a separation of the gas leakage and liquid leakage testing functions according to conducting dual testing at two different parts of the testing device- please see their Columns 1-4 along with Figures 1-2 for relevant details. Finally, the Examiner emphasizes that the air/gas bubble detectors of the cited prior art are regarded as being physically equivalent to an air infiltration detector since any air leaking into the dialysis fluid flowpath of pumped circulating blood would form a group of bubbles or microbubbles that are equilibrium dissolved into solution with the blood fluid; where air is known to be drawn into a liquid at the site of a leak/flaw/opening/crack under the effect of a reduced pressure [vacuum] acting on the pumped liquid [blood]- such facts Notoriously Old & Well Known via U.S. Patent No. 6,228,271 by Cote, M.P. dated May 08, 2001, for instance.

Allowable Subject Matter

5. Claims 5, 12-15, 25, 38-39, 40-42, 47 and 60-64 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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6. Claims 17-20 are allowable over the prior art of record.

7. The following is an Examiner's statement of reasons for the indication of allowable subject matter: The prior art fails to disclose a method and apparatus for detecting leaks in an extracorporeal blood circuit by detecting blood or liquid fluid outside a first portion of a blood circuit, and detecting air inside a second portion of the blood circuit that is remote from the first portion; which method and apparatus also has an alarm feature for signifying the occurrence of either or both types of fluid leakage detections at the two different blood circuit portions; where such system includes the further features of the objected to claims 5, 12-15, 25, 38-39, 40-42, 47 and 60-64.

8. The following is an Examiner's statement of reasons for allowance: The prior art fails to disclose a device for detecting leaks in a blood circuit by a first leak detector that senses blood outside the blood circuit by detecting blood leaks from a first portion of a blood circuit that is remote from the patient, and also by a second leak detector

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that detects air leaks into the blood circuit lines under an applied negative pressure inside a second portion of the blood circuit by sensing any air infiltration into blood circuit lines connecting the patient to the first portion; where a mechanism insures that at least part of such blood circuit lines are under negative pressure part of the time during a treatment that is remote from the first portion; with such dual leakage detecting device also having an alarm feature capable of signifying the occurrence of either or both types of fluid leakage detections at either or both of the two different blood circuit portions.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The references cited on the accompanying form PTO-892 are listed

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to show examples of state of the art apparatus and methods for determining the presence or absence of any type fluid leak condition in a liquid fluid circuit, and then actuating an alarm for warning of leakage event & system malfunction so as to commence a system shut-down in the interests of safety and environmental concerns [whether or not the fluid leak condition refers to a leaking air/ gas that is drawn/ pulled into the flowing circulating liquid under an applied low pressure; or a leaking liquid that seeps/escapes out of the flowing circulating liquid under an applied high pressure; and whether or not the liquid fluid is blood that flows for treatment thru a dialysis blood processing machine or extracorporeal blood cleaning/filtering circuit], which share one or more features in common with the instant invention.

10. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to J. David Wiggins whose telephone number is (703) 305-4884. The Examiner can normally be reached on Monday to Friday from 9AM to 7PM.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Hezron E. Williams, can be reached on (703) 305-4705. The fax phone number for this Group is (703) 308-7382.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 305-4900.



HEZRON WILLIAMS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2800



WIGGINS/jdw
May 16, 2003